EXHIBIT 9

Excerpts from the Rebuttal Expert Report of Jay W. Heinecke, M.D. Dated May 10, 2019

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

AMARIN PHARMA, INC. and AMARIN PHARMACEUTICALS IRELAND LIMITED Plaintiffs, v. HIKMA PHARMACEUTICALS USA INC. and HIKMA PHARMACEUTICALS INTERNATIONAL LIMITED, Defendants.	Case No. 2:16-cv-02525-MMD-NJK (CONSOLIDATED) Judge: Miranda M. Du **CONFIDENTIAL**

REBUTTAL EXPERT REPORT OF JAY W. HEINECKE, M.D. ON INVALIDITY OF THE ASSERTED CLAIMS OF THE PATENTS-IN-SUIT

also understand that failure of others is not particularly probative if it preceded publications that would render the invention obvious.

17. With respect to the secondary consideration of unexpected results, I understand that when unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art. I also understand that unexpected results that are probative of nonobviousness are those that are different in kind and not merely in degree from the results of the prior art.

18. Where appropriate, I have summarized my understanding of additional legal standards specific to certain claims and issues in my analysis below.

III. SUMMARY OF OPINIONS

19. Counsel for Defendants have asked me to respond to the opinions offered by Dr. Toth and Dr. Ismail in their opening reports regarding whether there is objective evidence that the asserted claims would not have been obvious to a POSA as of March 2008. In their reports, Dr. Toth and/or Dr. Ismail opine that (A) the claimed invention satisfied a long-felt unmet need in the prior art; (B) others failed to achieve the claimed invention; (C) the claimed invention produces unexpected results; (D) experts were skeptical of the claimed invention; and (E) the claimed invention has received industry praise. For the reasons discussed below, I disagree that there is any probative or relevant evidence of these objective indicia. Having reviewed Dr. Toth's and Dr. Ismail's report and the materials cited in those reports, it remains my opinion, for all of the reasons set forth in my opening report and below, that there is clear and convincing evidence that the asserted claims are invalid as obvious over the prior art.

20. I may testify at trial about the opinions discussed in this expert report and any supplemental reports or declarations that I may prepare for this case, as well as present a tutorial on background scientific concepts to better explain the context of the technology at issue. I may

also testify at trial regarding matters addressed by other witnesses, and prepare demonstratives to better help me explain my opinions. The bases for my opinions include the documents and prior art cited in this report, my education, and my years of experience and research. I reserve the right to amend or supplement my report if additional facts or information become available.

IV. LEVEL OF ORDINARY SKILL

21. In my opening report, I provided my opinion regarding the level of ordinary skill in the art to which the asserted patents pertain, which I applied in evaluating whether the asserted claims would have been obvious to a POSA as of March 2008. (Heinecke Opening Rept. ¶¶ 37-40.) In his opening report, Dr. Toth relies on a different definition of a POSA:

> [A] person of ordinary skill in the art in this case would be (1) a clinician with an M.D., or D.O. and at least 2 to 3 years of experience in the diagnosis, evaluation, and treatment of lipid blood disorders, including severe hypertriglyceridemia (*i.e.*, TG levels of at least 500 mg/dl) or (2), alternatively, a clinician, such as a nurse practitioner or physician's assistant, with 3 to 5 years of experience in the diagnosis, evaluation, and treatment of lipid blood disorders, including severe hypertriglyceridemia.

(Toth Opening Rept. ¶ 42.)

22. I disagree with Dr. Toth's definition of a POSA, which would include a nurse practitioner or physician's assistant. (*Id.*) In my opinion, the asserted patents are directed to a person with a higher level of ordinary skill than a nurse practitioner or physician's assistant. As I explained in my opening report, the POSA for purposes of the asserted patents would have had at least a medical degree or an advanced degree in the field of lipid biochemistry, and could have had a lower level of formal education only if she had a higher degree of industry experience. (Heinecke Opening Rept. ¶ 37.) I stand by the definition in my opening report.

23. Nevertheless, any difference between my definition of a POSA and Dr. Toth's is not material to my opinions in this case. My opinions regarding the obviousness of the asserted

claims are the same regardless of whose definition is adopted. My background and qualifications meet both definitions of a POSA today, and did so as of the earliest priority date in March 2008.

V. KEY CLINICAL STUDIES

24. Most of the alleged objective indicia of nonobviousness addressed in Dr. Toth's and Dr. Ismail's reports are based on the MARINE and REDUCE-IT clinical trials, which were each published after the priority date of the asserted patents. I disagree that either of these studies provides relevant evidence of nonobviousness.

25. Before the priority date, earlier published studies showed that EPA provides the same benefits that Dr. Toth and Dr. Ismail now rely on. I discussed many of those prior-art studies and publications in my opening report. (Heinecke Opening Rept. ¶¶ 62-114, 121-149, 153-184, 200-227.) For purposes of this report and the alleged objective indicia addressed by Dr. Toth and Dr. Ismail, a key prior-art study on EPA is the JELIS trial. Below, I briefly summarize these three studies—JELIS, MARINE, and REDUCE-IT—in chronological order.

A. JELIS

26. As discussed in my opening report, the results of the Japan EPA Lipid Intervention Study (JELIS) were reported in Yokoyama 2007,[1] which was published on March 31, 2007. (Heinecke Opening Rept. ¶¶ 207-11.) Yokoyama 2007, which I understand is prior art to the asserted patents, was peer-reviewed and published in *The Lancet*, one of world's most well-known and prestigious medical journals. (Yokoyama 2007.)

[1] Yokoyama et al., *Effects of Eicosapentaenoic Acid on Major Coronary Events in Hypercholesterolaemic Patients (JELIS): a Randomized Open-Label, Blinded Endpoint Analysis*, 369 Lancet 1090-98 (2007) ("Yokoyama 2007").

reduce cardiovascular risk; (2) Vascepa® does not embody the asserted claims; (3) none of the asserted claims require or recite a reduction in cardiovascular risk; (4) the asserted claims cover 12 weeks' treatment, whereas the REDUCE-IT results were observed only after a year or more; (5) the asserted claims require reducing triglycerides, yet the cardiovascular benefit observed in REDUCE-IT occurred regardless of triglyceride levels; (6) the asserted claims require baseline triglyceride levels of at least 500 mg/dl, whereas patients enrolled in REDUCE-IT had lower baseline levels; (7) some asserted claims require reducing or not increasing LDL-C, yet patients in REDUCE-IT experienced increases in LDL-C; and (8) some asserted claims exclude the use of statins, yet all patients in REDUCE-IT were taking them. (*Id*.) All of these reasons discussed above apply equally in the context of industry praise.

196. For all of these reasons, my opinion is that there is no relevant industry praise that provides objective evidence that the asserted claims would not have been obvious.

VII. CONCLUSION

197. In sum, for the reasons discussed above, it is my opinion that there is no objective evidence that the asserted claims would not have been obvious to a POSA as of March 2008. For the reasons discussed in my opening report, it remains my opinion that each of the asserted claims would have been obvious to a POSA as of March 2008 in view of the prior art.

I hereby declare that all of the statements made herein are true of my own knowledge and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: May 10, 19

Jay W. Heinecke, M.D.